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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,660	01/25/2002	Karlheinz Bortlik	88265-6773	4348

28765 7590 08/25/2003

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EXAMINER
DAVIS, RUTH A

ART UNIT	PAPER NUMBER
1651	8

DATE MAILED: 08/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	10/057,660	BORTLIK ET AL.	
	Examin r	Art Unit	
	Ruth A. Davis	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 June 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21 and 25-31* is/are pending in the application.

4a) Of the above claim(s) *25-31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *1* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Applicant's amendment and election with traverse of Group 1, claims 1 – 21 in Paper No. 6 is acknowledged. The traversal is on the ground(s) that the product by process claims must be examined based on the product and not the process, and may therefore be examined with the elected product claims. Applicant further argues that by searching the product claims, one must also search the process of making the product. This is not found persuasive because new claims 30 – 31 are drawn to a separate product than that claimed in claims 1 – 21. As such, the inventions are regarded as separate and distinct. Further the process of making has a separate classification than the elected product, requiring a different search than the claimed product. An overlapping search is not a coextensive search, as demonstrated by a reference that would anticipated one group would not necessarily anticipate or even make obvious the invention of another group.

The requirement is still deemed proper and is therefore made FINAL.

Claims 22 – 25 are canceled; claims 30 – 31 are added. Claims 1 – 21 and 25 – 31 are pending, claims 25 – 31 are withdrawn from consideration, and claims 1 – 21 have been considered on the merits.

Priority

2. Acknowledgment is made of applicant's claim for foreign priority based on applications filed in Europe on May 29, 2001 and May 30, 2000. It is noted, however, that applicant has not filed a certified copy of the PCT/EP01/06145 and EPO 00111542.7 applications as required by 35 U.S.C. 119(b).

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 is drawn to a composition however is rendered vague and indefinite for reciting "cereals" because it is unclear how a cereal is a plant.

Claim 16 is confusing because it is unclear what is part of the Markush group. Applicant may prefer to replace the first recitation of "and" with "or" in line 2 to more clearly claim the invention.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claim1 – 14, 16 and 18 – 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Fujiwara et al. (US 5705526 A).

Applicant claims a composition comprising at least one lipophillic bioactive compound (LBC) and a whey protein, wherein the protein is in an amount effective to increase the bioavailability of the bioactive compound. The LBC is obtained from plants selected from tomatoes, soya, green tea, green coffee bean, spices, grapes, cocoa, ginger or cereals; microorganisms of any bacterium, yeasts, or animal products selected from liver extract of milk fractions. The LBC is selected from carotenoids, polyphenols, lipophillic vitamins, flavonoids, isoflavones, curcuminoid, ceramide, proanthocyanidin, terpenoid, sterol, phytosterol, sterol ester, tocotrienol, squalene, retinoids, or mixtures thereof. Specifically, the LBC is a tomato extract, soybean extract or a mixture thereof. The composition is a powder, gel or liquid and further comprises vitamin C or tocopherol; or further comprises at least one of an emulsifier, stabilizer, or other additive. The LBC is 0.05 – 50% of the composition and the whey protein is 5 – 90%, or the ratio of whey protein to LBC is 1:1 – 500:1. The composition is incorporated into an oral

composition selected from a food stuff, supplement, cosmetic, or pharmaceutical preparation wherein the supplement further comprises at least one of a sweetener, stabilizer, flavoring or colorant; and is a sugar coated tablet, pill, gelatin capsule, syrup, gel or cream. Applicant claims a composition comprising 0.001 – 100% or 10 – 50% of the composition of claim 1, and a cosmetic comprising 10^-10 – 10% of the composition. Applicant additionally claims a composition comprising an LBC of a tomato oleoresin, a soybean extract or mixture thereof; and a whey protein in an amount effective to increase the bioavailability of the LBC.

Fujiwara teaches a pharmaceutical comprising lycopene (tomato oleoresin/LBC) (abstract), soybean oil (whey protein) and vitamin E (tocopherol) (col.5). The composition is a gelatin capsule (abstract), tablet or powder and may further contain emulsifiers, stabilizers, coating agents, and/or solvents (col.3 line 47-55). Specifically, the composition comprises 30mg lycopene and 8mg soybean (whey protein) (col.5).

Although the reference does not teach the source of the LBC, the patentability of a product does not depend on its method of production. If the claimed product is the same or obvious from a product in the prior art (i.e. the product disclosed in the cited reference), the claim is unpatentable even though the reference product was made by a different process. When the prior art discloses a product which reasonably appears to be identical with or slightly different than the claimed product-by-process, rejections under 35 U.S.C 102 and/or 35 U.S.C 103 are proper. (MPEP 2113) Further, although Fujiwara does not specifically teach oral or cosmetic compositions, the compositions are the same, as claimed.

Therefore the reference anticipates the claimed subject matter.

7. Claims 1 – 8, 10 – 16 and 18 – 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Potter et al. (US 5855892 A).

Applicant claims a composition comprising at least one lipophillic bioactive compound (LBC) and a whey protein, wherein the protein is in an amount effective to increase the bioavailability of the bioactive compound. The LBC is obtained from plants selected from tomatoes, soya, green tea, green coffee bean, spices, grapes, cocoa, ginger or cereals; microorganisms of any bacterium, yeasts, or animal products selected from liver extract of milk fractions. The LBC is selected from carotenoids, polyphenols, lipophillic vitamins, flavonoids, isoflavones, curcuminoid, ceramide, proanthocyanidin, terpenoid, sterol, phytosterol, sterol ester, tocotrienol, squalene, retinoids, or mixtures thereof. Specifically, the LBC is a tomato extract, soybean extract or a mixture thereof; and the composition further comprises at least one of an emulsifier, stabilizer, or other additive. The LBC is 0.05 – 50% of the composition, the whey protein is 5 – 90%; or the ratio of whey protein to LBC is 1:1 – 500:1. The composition is incorporated into an oral composition selected from a food stuff, supplement, cosmetic, or pharmaceutical preparation wherein the food stuff is a yogurt, drink, chocolate containing product, ice cream, cereal, coffee or animal food; and the supplement further comprises at least one of a sweetener, stabilizer, flavoring or colorant; and is a sugar coated tablet, pill, gelatin capsule, syrup, gel or cream. Applicant additionally claims a composition with 0.001 – 100% or 10 – 50% of the claimed composition, or a cosmetic comprising 10^-10 – 10% of the composition. Applicant additionally claims a composition comprising an LBC of a tomato oleoresin, a soybean extract or mixture thereof; and a whey protein in an amount effective to increase the bioavailability of the LBC.

Potter teaches pharmaceutical/supplement compositions comprising daidzein (LBC, isoflavone from soy), soy whey protein (abstract, col.6 line 60-63) and vitamins. The compositions are formulated into pills, capsules, powder or solutions and may contain carriers, binders, diluents, excipients (col.5 line 47-56), colorings and/or flavoring (col.6 line 7-8). The compositions may also be incorporated into foods, drinks, ice cream, or yogurt (col.6 line 13-30). Specifically, the compositions comprise 5 – 90% diadzein rich soy protein (or combined LBC and whey protein) (formulations).

Although the reference does not teach the source of the LBC, the patentability of a product does not depend on its method of production. If the claimed product is the same or obvious from a product in the prior art (i.e. the product disclosed in the cited reference), the claim is unpatentable even though the reference product was made by a different process. When the prior art discloses a product which reasonably appears to be identical with or slightly different than the claimed product-by-process, rejections under 35 U.S.C 102 and/or 35 U.S.C 103 are proper. (MPEP 2113) Further, although Potter does not specifically teach oral or cosmetic compositions, the compositions are the same, as claimed.

Therefore the reference anticipates the claimed subject matter.

8. Claims 1 – 10, 13 – 14, 16 and 18 – 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Schmitz et al. (US 5643623 A).

Applicant claims a composition comprising at least one lipophillic bioactive compound (LBC) and a whey protein, wherein the protein is in an amount effective to increase the bioavailability of the bioactive compound. The LBC is obtained from plants selected fro

tomatoes, soya, green tea, green coffee bean, spices, grapes, cocoa, ginger or cereals; microorganisms of any bacterium, yeasts, or animal products selected from liver extract of milk fractions. The LBC is selected from carotenoids, polyphenols, lipophillic vitamins, flavonoids, isoflavones, curcuminoid, ceramide, proanthocyanidin, terpenoid, sterol, phytosterol, sterol ester, tocotrienol, squalene, retinoids, or mixtures thereof. Specifically, the LBC is a tomato extract, soybean extract or a mixture thereof. The composition is a powder, gel or liquid and further comprises vitamin C or tocopherol; or further comprises at least one of an emulsifier, stabilizer, or other additive; or is incorporated into an oral composition selected from a food stuff, supplement, cosmetic, or pharmaceutical preparation wherein the supplement further comprises at least one of a sweetener, stabilizer, flavoring or colorant; and is a sugar coated tablet, pill, gelatin capsule, syrup, gel or cream. Applicant claims a composition comprising 0.001 – 100% or 10 – 50% of the composition, or a cosmetic comprising 10^-10 – 10% of the composition. Applicant additionally claims a composition comprising an LBC of a tomato oleoresin, a soybean extract or mixture thereof; and a whey protein in an amount effective to increase the bioavailability of the LBC.

Schmitz teaches food product compositions comprising lycopene, vitamin C, E, whey protein, flavors and colors (abstract, example 6) in forms of solid, gels or liquids (col.4 line 8-17).

Although the reference does not teach the source of the LBC, the patentability of a product does not depend on its method of production. If the claimed product is the same or obvious from a product in the prior art (i.e. the product disclosed in the cited reference), the claim is unpatentable even though the reference product was made by a different process. When

the prior art discloses a product which reasonably appears to be identical with or slightly different than the claimed product-by-process, rejections under 35 U.S.C 102 and/or 35 U.S.C 103 are proper. (MPEP 2113) Further, although Schmitz does not specifically teach oral or cosmetic compositions, the compositions are the same, as claimed.

Therefore the reference anticipates the claimed subject matter.

9. Claims 1 – 7, 9 – 13, 17 and 20 – 21 are rejected under 35 U.S.C. 102(a) and 102(e) as being anticipated by Collins et al. (US 6203805 B1).

Applicant claims a composition comprising at least one lipophillic bioactive compound (LBC) and a whey protein, wherein the protein is in an amount effective to increase the bioavailability of the bioactive compound. The LBC is obtained from plants selected from tomatoes, soya, green tea, green coffee bean, spices, grapes, cocoa, ginger or cereals; microorganisms of any bacterium, yeasts, or animal products selected from liver extract of milk fractions. The LBC is selected from carotenoids, polyphenols, lipophillic vitamins, flavonoids, isoflavones, curcuminoid, ceramide, proanthocyanidin, terpenoid, sterol, phytosterol, sterol ester, tocotrienol, squalene, retinoids, or mixtures thereof. The composition is a powder, gel or liquid and further comprises vitamin C or tocopherol; or further comprises at least one of an emulsifier, stabilizer, or other additive. The LBC is 0.05 – 50% of the composition and the whey protein is 5 – 90%; or the ratio of whey protein to LBC is 1:1 – 500:1. The composition further comprises a compound active to the skin, is a cosmetic and is present at 10^-10 – 10%. Applicant additionally claims a composition comprising an LBC of a tomato oleoresin, a soybean extract or

mixture thereof; and a whey protein in an amount effective to increase the bioavailability of the LBC.

Collins teaches topical, cosmetic and pharmaceutical compositions comprising whey protein, vitamin A, C and E (abstract, col.2 line 9-18). The compositions may further include other skin care ingredients, carriers, emulsifiers, stabilizers, preservatives or flavorings (col.5 line 35-65) and can be formed as liquids, emulsions, creams, gels and/or suspensions (col.5 line 23-30). Specifically, the whey protein is in amounts of 50 – 10,000ug/ml and the vitamin A is 1 – 100ug/ml (col.4 line 66 – col.5 line5).

Although the reference does not teach the source of the LBC, the patentability of a product does not depend on its method of production. If the claimed product is the same or obvious from a product in the prior art (i.e. the product disclosed in the cited reference), the claim is unpatentable even though the reference product was made by a different process. When the prior art discloses a product which reasonably appears to be identical with or slightly different than the claimed product-by-process, rejections under 35 U.S.C 102 and/or 35 U.S.C 103 are proper. (MPEP 2113)

Therefore the reference anticipates the claimed subject matter.

10. Claims 1 – 7, 11 – 14 and 18 – 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Rosenberg.

Applicant claims a composition comprising at least one lipophillic bioactive compound (LBC) and a whey protein, wherein the protein is in an amount effective to increase the bioavailability of the bioactive compound. The LBC is obtained from plants selected from

tomatoes, soya, green tea, green coffee bean, spices, grapes, cocoa, ginger or cereals; microorganisms of any bacterium, yeasts, or animal products selected from liver extract of milk fractions. The LBC is selected from carotenoids, polyphenols, lipophillic vitamins, flavonoids, isoflavones, curcuminoid, ceramide, proanthocyanidin, terpenoid, sterol, phytosterol, sterol ester, tocotrienol, squalene, retinoids, or mixtures thereof. The LBC is 0.05 – 50% of the composition and the whey protein is 5 – 90%; or the ratio of whey protein to LBC is 1:1 – 500:1. The composition is incorporated into an oral composition selected from a food stuff, supplement, cosmetic, or pharmaceutical preparation and is present at 0.001 – 100% or 10 – 50%; or is a cosmetic present at 10^-10 – 10%. Applicant additionally claims a composition comprising an LBC of a tomato oleoresin, a soybean extract or mixture thereof; and a whey protein in an amount effective to increase the bioavailability of the LBC.

Rosenberg teaches a composition comprising 10 – 75% vitamin A and 35 – 80% whey protein (example 6).

Although the reference does not teach the source of the LBC, the patentability of a product does not depend on its method of production. If the claimed product is the same or obvious from a product in the prior art (i.e. the product disclosed in the cited reference), the claim is unpatentable even though the reference product was made by a different process. When the prior art discloses a product which reasonably appears to be identical with or slightly different than the claimed product-by-process, rejections under 35 U.S.C 102 and/or 35 U.S.C 103 are proper. (MPEP 2113) Further, although Rosenberg does not specifically teach oral or cosmetic compositions, the compositions are the same, as claimed.

Therefore the reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 1 – 16 and 18 – 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Potter and/or Fujiwara.

Applicant claims a composition comprising at least one lipophillic bioactive compound (LBC) and a whey protein, wherein the protein is in an amount effective to increase the bioavailability of the bioactive compound. The LBC is obtained from plants selected from tomatoes, soya, green tea, green coffee bean, spices, grapes, cocoa, ginger or cereals; microorganisms of any bacterium, yeasts, or animal products selected from liver extract of milk

fractions. The LBC is selected from carotenoids, polyphenols, lipophillic vitamins, flavonoids, isoflavones, curcuminoid, ceramide, proanthocyanidin, terpenoid, sterol, phytosterol, sterol ester, tocotrienol, squalene, retinoids, or mixtures thereof. Specifically, the LBC is a tomato extract, soybean extract or a mixture thereof; the composition is a powder, gel or liquid and further comprises vitamin C or tocopherol; or further comprises at least one of an emulsifier, stabilizer, or other additive; the LBC is 0.05 – 50% of the composition and the whey protein is 5 – 90%; or the ratio of whey protein to LBC is 1:1 – 500:1. The composition is incorporated into an oral composition selected from a food stuff, supplement, cosmetic, or pharmaceutical preparation wherein the food stuff is a yogurt, drink, chocolate containing product, ice cream, cereal, coffee or animal food, and the supplement further comprises at least one of a sweetener, stabilizer, flavoring or colorant; and is a sugar coated tablet, pill, gelatin capsule, syrup, gel or cream. Applicant claims a composition comprising 0.001 – 100% or10 – 50% of the composition, or a cosmetic with 10^-10 – 10% of the composition. Applicant additionally claims a composition comprising an LBC of a tomato oleoresin, a soybean extract or mixture thereof; and a whey protein in an amount effective to increase the bioavailability of the LBC.

Potter teaches pharmaceutical/supplement compositions comprising daidzein (LBC, isoflavone from soy), soy whey protein (abstract, col.6 line 60-63) and vitamins. The compositions are formulated into pills, capsules, powder or solutions and may contain carriers, binders, diluents, excipients (col.5 line 47-56), colorings and/or flavoring (col.6 line 7-8). The compositions may also be incorporated into foods, drinks, ice cream, or yogurt (col.6 line 13-30). Specifically, the compositions comprise 5 – 90% diadzein rich soy protein (or combined LBC

and whey protein) (formulations). Potter teaches the composition is effective to decrease LDL and increase HDL (abstract).

Fujiwara teaches a pharmaceutical comprising lycopene (tomato oleoresin/LBC) (abstract), soybean oil (whey protein) and vitamin E (tocopherol) (col.5). The composition is a gelatin capsule (abstract), tablet or powder and may further contain emulsifiers, stabilizers, coating agents, and/or solvents (col.3 line 47-55). Specifically, the composition comprises 30mg lycopene and 8mg soybean (whey protein) (col.5). Fujiwara teaches the composition is effective to decrease LDL and increase HDL (col.7 line32-43).

The references do not teach a composition comprising lycopene, soy extract and whey protein. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to combine the instant ingredients for their known benefit, as disclosed by the cited references above, since each is well known in the art to decrease LDL and increase HDL. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by Potter and Fujiwara to combine the instant ingredients with a reasonable expectation for successfully obtaining a composition effective to lower LDL and increase HDL. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman,* 1943 C.D. 518.

Although the references do not teach the source of the LBC, the patentability of a product does not depend on its method of production. If the claimed product is the same or obvious from a product in the prior art (i.e. the product disclosed in the cited reference), the claim is unpatentable even though the reference product was made by a different process. When the prior

art discloses a product which reasonably appears to be identical with or slightly different than the claimed product-by-process, rejections under 35 U.S.C 102 and/or 35 U.S.C 103 are proper. (MPEP 2113) Further, although the references do not specifically teach oral or cosmetic compositions, the compositions are the same, as claimed.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

14. Claims 1 – 16 and 18 – 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schmitz.

Applicant claims a composition comprising at least one lipophillic bioactive compound (LBC) and a whey protein, wherein the protein is in an amount effective to increase the bioavailability of the bioactive compound. The LBC is obtained from plants selected from tomatoes, soya, green tea, green coffee bean, spices, grapes, cocoa, ginger or cereals; microorganisms of any bacterium, yeasts, or animal products selected from liver extract of milk fractions. The LBC is selected from carotenoids, polyphenols, lipophillic vitamins, flavonoids, isoflavones, curcuminoid, ceramide, proanthocyanidin, terpenoid, sterol, phytosterol, sterol ester, tocotrienol, squalene, retinoids, or mixtures thereof. Specifically, the LBC is a tomato extract, soybean extract or a mixture thereof; the composition is a powder, gel or liquid and further comprises vitamin C or tocopherol; or further comprises at least one of an emulsifier, stabilizer, or other additive; the LBC is 0.05 – 50% of the composition and the whey protein is 5 – 90%; or the ratio of whey protein to LBC is 1:1 – 500:1. The composition is incorporated into an oral composition selected from a food stuff, supplement, cosmetic, or pharmaceutical preparation

wherein the food stuff is a yogurt, drink, chocolate containing product, ice cream, cereal, coffee or animal food, and the supplement further comprises at least one of a sweetener, stabilizer, flavoring or colorant; and is a sugar coated tablet, pill, gelatin capsule, syrup, gel or cream. Applicant claims a composition comprising 0.001 – 100% or10 – 50% of the composition, or a cosmetic with 10^-10 – 10% of the composition. Applicant additionally claims a composition comprising an LBC of a tomato oleoresin, a soybean extract or mixture thereof; and a whey protein in an amount effective to increase the bioavailability of the LBC.

Schmitz teaches food product compositions comprising lycopene, vitamin C, E, whey protein, flavors and colors (abstract, example 6) in forms of solid, gels or liquids (col.4 line 8-17).

Schmitz does not teach the composition comprising the specific amounts and ratios of LBC and whey protein, or wherein the composition is in the claimed food forms. However, at the time of the claimed invention, it would have been well within the purview of one of ordinary skill in the art to optimize such amounts and forms as a matter of routine experimentation. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practice to optimize the various parameters of the compositions of Schmitz with a reasonable expectation for successfully obtaining a food product.

Although the reference does not teach the source of the LBC, the patentability of a product does not depend on its method of production. If the claimed product is the same or obvious from a product in the prior art (i.e. the product disclosed in the cited reference), the

different than the claimed product-by-process, rejections under 35 U.S.C 102 and/or 35 U.S.C 103 are proper. (MPEP 2113) Further, although Schmitz does not specifically teach oral or cosmetic compositions, the compositions are the same, as claimed.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 703-308-6310. The examiner can normally be reached on M-H (7:00-4:30); altn. F (7:00-3:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 703-308-0196. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ruth A. Davis; rad
August 18, 2003

LEON B. LANKFORD, JR.
PRIMARY EXAMINER